उत्पाद मैन्युअल
चिकित्सा विद्युत उपकरण
भाग 2 बुनियादी सुरक्षा और आवश्यक प्रदर्शन निष्पादन के लिए विशेष आवश्यकताएँ
धारा 50 शिशु फोटोथेरपी उपकरण
आई एस 13450 (भाग 2 / अनुभाग 50): 2022 / आई ई सी 60601-2-50 : 2020

PRODUCT MANUAL FOR
Medical Electrical Equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Sec 50 Infant Phototherapy Equipment
IS 13450 (Part 2 / Sec 50): 2022 / IEC 60601-2-50: 2020

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो) अनुरूपता मूल्यांकन (विनियम, 2018 की योजना -I के तहत प्रमाणन के संचालन में एकरूपता और पारदर्शिता के लिए इस उत्पाद मैनुअल का उपयोग सभी क्षेत्रीय / शाखा कार्यालयों और लाइसेंसधारियों द्वारा संदर्भ सामग्री के रूप में किया जाएगा। दस्तावेज़ का उपयोग बीआईएस प्रमाणन प्राप्त करने के इच्छुक संभावित आवेदकों द्वारा भी किया जा सकता हैI

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure uniformity of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations,2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification.

1.	**मानक संख्या** **IS No.**	:	IS 13450 (Part 2 / Sec 50): 2022 / IEC 60601-2-50: 2020
	शीर्षक **Title**	:	Medical Electrical Equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Sec 50 Infant Phototherapy Equipment
	संशोधनों की संख्या **No. of amendments**	:	Nil
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चामाल** **Raw material**	:	Components – As per Cl 4.8 of IS 13450 (Part 1):2018
b)	**समूहीकरण दिशानिर्देश** **Grouping Guidelines**	:	Please refer **ANNEX – A**
c)	**नमूने का परिमाण** **Sample Quantity**	:	1 machine (with all the accessories)
3.	**परीक्षण उपकरणों की सूची** **List of Test Equipment**	:	Please refer **ANNEX – B**

4.	**निरीक्षण और परीक्षण की स्कीम Scheme of Inspection and Testing**	:	Please refer **ANNEX – C**
5.	**एक दिन में संभावित परीक्षण Possible tests in a day**	:	1. Leakage currents & Patient auxiliary currents, Cl 201.8 2. Protective means, 201.9.5.1 3. Acoustic energy, 201.9.6.2 4. Irradiance distribution, 201.12.1.101 5. TOTAL IRRADIANCE FOR BILIRUBIN Ebi after pre-ageing, 201.12.1.105 6. Local distribution, 201.12.1.106 7. Power supply fluctuation, 201.13.2.101
6.	**लाइसेंस का दायरा /Scope of the Licence:**		

"License is granted to use Standard Mark as per ***IS 13450 (Part 2 / Sec 50): 2022 / IEC 60601-2-50: 2020*** with the following scope:

Name of the product	Medical Electrical Equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Sec 50 Infant Phototherapy Equipment
Model	
Rating	Rated Voltage …..V (or) Rated Voltage Ranges(s) ……V, ac Frequency …. Hz, Single phase / Three Phase, Rated Current …. A, Input power …….W (or) ….kVA
Internal Power Source	With / without internal power source
Type	Stationary (or) Fixed / Mobile / Portable
Protection against electric shock	Class – I / Class – II
Protection against harmful ingress of water or particulate matter	
Suitability for use in oxygen rich environment	Suitable/ Not suitable
Accessories to be supplied with the Infant Phototherapy Equipment	

ANNEX -A
Grouping Guidelines

1. Manufacturer shall submit the declaration for each of the parameters as specified in scope of the licence (as per Sl. No. 6 above) of each model of 'Infant Phototherapy Equipment' they intend to cover in the scope of licence.

2. For Grant of Licnce/ Change in Scope of Licence, each 'Model' of 'Infant Phototherapy Equipment' is to be tested. However, change in aesthetic (i.e. colour, visual design, etc) may not be treated as different model.

3. During the operation of the Licence, BO shall ensure that all the model(s) covered in the Scope of the Licence are tested in rotation to the extent possible.

Note: Firm shall declare the following parameters for each of the Model of Infant Phototherapy Equipment:

a) Any associated accessories supplied with the Infant Phototherapy Equipment (such as Weighing scale or integral bed)

ANNEX- B
LIST OF TEST EQUIPMENTS
(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	Tests used in with Clause Reference	Test Equipment
1.	Power Input, 4.11	Power Input Test Apparatus/Power Analyzer / Multimeter
2.	Durability of markings, 7.1.3	Distilled water, ethanol 96%, Isopropyl alcohol, Stop watch
3.	Impedance and current carrying capability, 8.6.4	AC/DC voltage source, multimeter
4.	Earth Leakage Current, 8.7.4.5, Touch Current, 8.7.4.6, Patient Leakage Current, 8.7.4.7	Leakage Current Tester, Metal foil Test Pin as per Figure 8 or a particular tool as specified by manufacture; Electrical safety analyzer
5.	Dielectric Strength, 8.8.3	High Voltage Tester
6.	Thermal Cycling Test, 8.9.3.4	Oven
7.	Protection against excessive temperatures and other hazards, 201.11	Temp. Data logger
8.	Acoustic energy, 201.9.6.2	Acoustic Wattmeter
9.	Irradiance distribution, Oven,201.12.1.101	Lux meter (Irradiance meter)
10.	Supports and mounting brackets for ACCESSORIES, 201.9.8.101 Barriers, 201.9.8.3.101	Force guage meter, Stopwatch
11.	Weighing scale, 201.12.1.107	Weights (500gm, 2000 gm)

Note 1: The licensee shall maintain a Technical file and Risk Management File as per the provisions of IS 13450 (Part 2 / Sec 50): 2022 / IEC 60601-2-50: 2020 for each model in the scope of license.

Note 2: The Technical File and Risk Management File shall be maintained by the licensee till the End of Life for each model.

ANNEX C
SCHEME OF INSPECTION AND TESTING

1. QUALITY ASSURANCE PLAN

1.1. It is expected that manufacturers (licensees/applicants) will implement a Quality Assurance Plan i.e. a plan of regular testing and in-process controls, designed to ensure that the product bearing the Standard Mark conforms to all requirements of the Indian Standard.

1.2 The manufacturers shall define a Quality Assurance Plan defining the control unit (i.e. lot/batch etc.) and the levels of control (i.e. the frequency and number of samples for conducting the different tests as per the Indian Standard) and submit the same to BIS Branch Office for information. The manufacturer shall comply with the same and maintain test records in accordance with para 2.4.

1.3 RECOMMENDED LEVELS OF CONTROL/CONTROL UNIT:

1.3.1 For the guidance of manufacturers in preparing the Quality Assurance Plan, recommended levels of control are given in Table 1.

1.3.2 The manufacturer shall ensure inspection and testing as per the Quality Assurance Plan submitted by them on the whole production of the factory which is covered by this plan. Alternatively, the manufacturer has the option of adherence to the quality plan as per levels of control recommended in column 3 of Table 1.

1.4 However, all manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard.

2. **ENSURING COMPLIANCE THROUGH TESTING**- It is expected that manufacturers (licensees/applicants) will establish a suitably equipped and staffed in house laboratory (In house testing facility) for testing at least those parameters of the Indian Standard which require routine testing for ensuring quality of the product. This includes in-process controls as may be defined and put in place by the manufacturer and testing parameters/requirements which can only be performed in the factory.

2.1 For the guidance of manufacturers, Table 1 giving the recommended levels of control is given below. Column 2 of Table 1 indicates routine tests where test equipment is required in house as "R" or other tests which can be subcontracted as "S". Subcontracting is permitted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

2.2 For MSME manufacturers, the requirement of maintaining a laboratory/in-house testing facility for routine tests (indicated as "R" in Column 2 of Table 1) is also optional.

2.2.1 MSME manufacturers may utilize common cluster based facilities as per guidelines for the utilization of cluster based test facilities by MSMEs or the provisions of Sharing of testing facilities or get testing done from BIS recognized/empaneled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

2.3 **Large Scale manufacturers shall maintain an in-house laboratory equipped at least with test facilities for routine tests (indicated as "R" in Column 2 of Table 1)**, where different tests given in the specification shall

be carried out in accordance with the method given in the specification. They shall also implement a calibration plan for the in-house test equipment.

2.3.1 Alternatively, in lieu of an in-house laboratory, large scale manufacturers can also utilize the provisions of Sharing of testing facilities as per the Guidelines for Grant of Licence available on BIS website www.bis.gov.in. (Under Conformity Assessment>Product Certification Process). Even for subcontracted tests, provisions for sharing of testing facilities can be utilized.

2.4 **TEST RECORDS**- The manufacturers maintaining an in-house laboratory or utilizing common cluster based facilities or shared test facilities shall maintain test records for the tests carried out to establish conformity. For the tests being subcontracted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025, test reports issued by the laboratories shall be available for inspection by BIS.

2.5.1 TECHNICAL FILE- Licencee shall maintain a Technical File for each model being manufactured by them. The Technical file shall be submitted to BIS at the time of Grant of Licence/ inclusion/ surveillance.

2.5.1.1 The Technical File shall be maintained till the End of Life of the model.

2.5.1.2 Licencee shall declare the frequency of periodic review of Technical file to BIS and record of review shall be maintained. In case of any change in the Technical file due to any periodic review/ change in the product, the licencee shall inform the same to BIS and submit the copy of the latest version of Technical File to BIS within 30 days of issue of the revised/ modified Technical File.

2.5.1.3 For changes in the product which shall affect the Scope of the Licence, the modified product shall be treated as a different model and separate Technical File shall be maintained for the same.

2.5.1.4 The technical file shall consist of the following documents:

- A general description of the product;
- Product Manual and/ or Instructions for use;
- Instructions for repair/ service for the product/ components, if required;
- Frequency of periodic repair/ service for the product/ components, if required;
- Conceptual product design and manufacturing drawings and, where appropriate, list of components, electrical circuit design, etc with descriptions and explanations needed for the understanding of these drawings;
- A list of the all Indian/ International standards applied in full or in part during the conformity assessment process with copy of test certificate/ test report;
- Test reports/ Test Certificates and risk assessment file for the product and/ or components as per relevant Clauses of the Indian Standard;
- Copies of conformity assessment documentation for critical product components and accessories;

2.5.2 RISK MANAGEMENT FILE- The licencee shall maintain a Risk Management File for each model of Infant Phototherapy Equipment as per the requirement of IS 13450 (Part 2 / Sec 50): 2022 / IEC 60601-2-50: 2020. The Risk Management File shall be submitted to BIS at the time of Grant of Licence/Inclusion/Surveillance.

2.5.2.1 The Risk Management File shall be maintained till the End of Life of each model.

2.5.2.2 Licencee shall declare the frequency of periodic review of Risk Management File to BIS and record of review shall be maintained. In case of any change in the Risk Management File due to any periodic review/ change in the product, the licencee shall inform the same to BIS and submit the copy of the latest version of Risk Management File to BIS within 30 days of issue of the revised/ modified Risk Management File.

3. PACKING AND MARKING - The Standard Mark as given in the Schedule of the licence shall be incorporated legibly and indelibly on each Infant Phototherapy Equipment provided always that the Infant Phototherapy Equipment so marked conforms to each requirement of the specification.

3.1 Marking shall be done as per Cl. 201.7 of IS 13450 (Part 2 / Sec 50): 2022 / IEC 60601-2-50: 2020.

3.2 **Additional Marking requirements**: The Infant Phototherapy Equipment shall also be marked with the following additional requirement on each product and its packaging:

a) "For BIS certification details please visit www.bis.gov.in"

3.3 All the production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the Standard Mark.

4. HYGIENIC CONDITIONS (if applicable) – NA.

5. REJECTION - Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act,2016.

TABLE-1

(1)				(2)	(3)		
Test Details				Test Equipment requirement R: Required (or) S: Sub-contracting permitted	Levels of Control		
Cl.	Requirement	Test Method			No. of Sample	Frequency	Remarks
		Clause	Reference				
201.4	**General requirements**						
4.1	Conditions for application to ME EQUIPMENT or ME SYSTEMS	4.1	IS 13450 (Part 1)	R	Each Medical Equipment		Technical documentation - Compliance shall be checked by inspection of the RISK MANAGEMENT FILE.
4.2	Risk management process for ME equipment or ME systems	4.2.1 4.2.2 4.2.3	IS 13450 (Part 1)	R			
4.3	Essential Performance	4.3	IS 13450 (Part 1)	R			No additional ESSENTIAL PERFORMANCE requirements for INFANT PHOTOTHERAPY EQUIPMENT
4.4	EXPECTED SERVICE LIFE	4.4	IS 13450 (Part 1)	R	Each Medical Equipment		Technical documentation - Compliance shall be checked by inspection of the RISK MANAGEMENT FILE.
4.5	Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	4.5	IS 13450 (Part 1)	R			
4.6	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	4.6	IS 13450 (Part 1)	R			

4.7	SINGLE FAULT CONDITION for ME EQUIPMENT	13.1 13.2	IS 13450 (Part 1)	S	One	Once in a month for each type of model manufactured during that period	
4.8	Components of ME EQUIPMENT	4.8	IS 13450 (Part 1)	R	One	Each Consignment	No further testing if accompanied with Test Certificate or ISI Mark or covered in Risk Management file
4.9	Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT	4.9	IS 13450 (Part 1)				
4.10	**Power supply**						
4.10.1	Source of power for ME EQUIPMENT	4.10.1	IS 13450 (Part 1)	R	Each Medical Equipment		Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
4.10.2	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS	4.10.2	IS 13450 (Part 1)	R			
4.11	Power input	4.11	IS 13450 (Part 1)	R			
201.7	**ME Equipment identification, marking and documents**						
7	ME Equipment Identification, marking and documents	7	IS 13450 (Part 1)	R	Each Medical Equipment		
201.7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts ACCESSORIES	201.7.2	IS 13450 (Part 1)	R			
	Safety sign for PATIENT eye shield	201.7.2.101	IS 13450-2-50	R			

7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts	7.3	IS 13450 (Part 1)	R		
	Heating elements or lamp holders	201.7.3.1	IS 13450-2-50	R		
7.4	Marking of controls and instruments	7.4	IS 13450 (Part 1)	R		
7.5	Safety signs	7.5		R		
7.6	Symbols	7.6		R	Each Medical Equipment	
7.7	Colours of the insulation of conductors	7.7	IS 13450 (Part 1)	R		
7.8	Indicator lights and controls	7.8	IS 13450 (Part 1)	R		
7.9	ACCOMPANYING DOCUMENTS	7.9	IS 13450 (Part 1)	R		
	Warning and safety notices	201.7.9.2.2	IS 13450-2-50	R		
	ME EQUIPMENT description	201.7.9.2.5	IS 13450-2-50	R		
	Operating instructions	201.7.9.2.9	IS 13450-2-50	R		
	Maintenance	201.7.9.2.13	IS 13450-2-50	R		
	ACCESSORIES, supplementary equipment, used material	201.7.9.2.14	IS 13450-2-50	R		

201.8	**Protection against electrical hazards from ME Equipment**						
8.1	Fundamental rule of protection against electric shock	8.1	IS 13450 (Part 1)	R	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File	
8.2	Requirements related to power sources	8.2	IS 13450 (Part 1)	R			
8.3	Classification of APPLIED PARTS	8.3	IS 13450 (Part 1)	R			
8.4	Limitations of voltage, current or energy	8.4	IS 13450 (Part 1)	S	One	Once in a month for each type of model manufactured during that period	
8.5	Separation of Parts	8.5	IS 13450 (Part 1)	S	One	Once in a month for each type of model manufactured during that period	
8.6							
8.6	Protective earthing, functional earthing and potential equalization of ME EQUIPMENT	8.6	IS 13450 (Part 1)	S	One	Once in a month for each type of model manufactured during that period	
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	8.7	IS 13450 (Part 1)	S			
8.8	Insulation	8.8	IS 13450 (Part 1)	S			
8.9	CREEPAGE DISTANCES and AIR CLEARANCES	8.9	IS 13450 (Part 1)	S	One	Once in a month for each type of model manufactured during that period	
8.10	Components and wiring	8.10	IS 13450 (Part 1)	S	One		
8.11	MAINS PARTS, components and layout	8.11	IS 13450 (Part 1)	S	One	Once in a month for each type of model manufactured during that period	
201.9	**Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS**						

9.1	MECHANICAL HAZARDS of ME EQUIPMENT	9.1	IS 13450 (Part 1)	S	One	Once in a month for each type of model manufactured during that period
9.2	MECHANICAL HAZARDS associated with moving parts	9.2	IS 13450 (Part 1)	S	One	
9.3	MECHANICAL HAZARD associated with surfaces, corners and edges	9.3	IS 13450 (Part 1)	S	One	
9.4	Instability HAZARDS	9.4,	IS 13450 (Part 1)	S	One	Once in a month for each type of model manufactured during that period
9.5	Expelled parts HAZARD Protective means	9.5 201.9.5.1	IS 13450 (Part 1) IS 13450-2-50	S	One	
9.6	Audible acoustic energy Acoustic energy	9.6 201.9.6.2	IS 13450 (Part 1) IS 13450-2-50	S	One	
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure	9.7	IS 13450 (Part 1)	S	One	
9.8	MECHANICAL HAZARDS associated with support systems Supports and mounting brackets for ACCESSORIES Barriers	9.8 201.9.8.101 201.9.8.3.101	IS 13450 (Part 1) IS 13450-2-50 IS 13450-2-50	S	One	

201.10	**Protection against unwanted and excessive radiation HAZARDS**					
10.1	X-Radiation	10.1	IS 13450 (Part 1)	S	One	Once in every three years for each type of model manufactured during that period
10.2	Alpha, beta, gamma, neutron and other particle radiation	10.2	IS 13450 (Part 1)	S	One	
10.3	Microwave radiation	10.3	IS 13450 (Part 1)	S	One	
10.4	Lasers	10.4	IS 13450 (Part 1)	S	One	
10.5	Other visible electromagnetic radiation	10.5	IS 13450 (Part 1)	S	One	
10.6	Infrared radiation	10.6	IS 13450 (Part 1)	S	One	
10.7	Ultraviolet radiation	10.7	IS 13450 (Part 1)	S	One	
201.11	**Protection against excessive temperatures and other HAZARDS**					
11.1	Excessive temperatures in ME EQUIPMENT APPLIED PARTS not intended to supply heat to a PATIENT	11.1 201.11.1.2.2	IS 13450 (Part 1) IS 13450-2-50	S	One	Once in a moth for each type of model manufactured during that period
11.2	Fire Prevention	11.2	IS 13450 (Part 1)	S	One	
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT	11.3	IS 13450 (Part 1)	S	One	
11.4	ME EQUIPMENT and ME SYSTEMS	11.4	IS 13450 (Part 1)	S	One	

	intended for use with flammable anaesthetics						
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents	11.5	IS 13450 (Part 1)	S	One		
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT	11.6	IS 13450 (Part 1)	R	One		
11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS	11.7	IS 13450 (Part 1)	R	One	Once in 03 years	
11.8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	11.8 201. 11.8	IS 13450 (Part 1) IS 13450-2-50	R	Every Medical Equipment		
201.12	**Accuracy of controls and instruments and protection against hazardous outputs**						
12.1	Accuracy of controls and instruments Irradiance distribution	12.1 201.12.1.101	IS 13450 (Part 1) IS 13450-2-50	R	Each Medical Equipment		

	Measuring principles	201.12.1.102	IS 13450-2-50	R			
	Spectral method	201.12.1.103		R			
	Integral method	201.12.1.104		R			
	TOTAL IRRADIANCE FOR BILIRUBIN Ebi after pre-ageing	201.12.1.105		R			
	Local distribution	201.12.1.106		R			
	Weighing scale	201.12.1.107		R			
12.2	USABILITY of ME EQUIPMENT	12.2	IS 13450 (Part 1)	R			
12.3	ALARM SYSTEMS	12.3	IS 13450 (Part 1)	R			
201.13	**HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT**						
13	HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	13	IS 13450 (Part 1)	S	One	Once in a month for each type of model manufactured during that period	
	Power supply fluctuation	201.13.2.101	IS 13450-2-50				
201.14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**						
14	Programmable Electrical Medical Systems (PEMS)	14	IS 13450 (Part 1)	S	One	Once in 03 years	For each type of model manufactured during the period
201.15	**Construction of ME EQUIPMENT**						
15.1	Arrangements of controls and indicators	15.1	IS 13450 (Part 1)	S	One	Once in every six month for each type of model manufactured during that period	

	of ME EQUIPMENT						
15.2	Serviceability	15.2	IS 13450 (Part 1)	S			
15.3	Mechanical strength	15.3	IS 13450 (Part 1)	S	One	Once in every six month for each type of model manufactured during that period	
15.4	Indicators Examination of the lifetime	15.4 201.15.4.4.101	IS 13450 (Part 1) IS 13450-2-50	S	One	Once in every six month for each type of model manufactured during that period	
201.16	**ME SYSTEMS**						
16	ME SYSTEMS	16	IS 13450 (Part 1)	S	Each Medical Equipment		Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
201.17	**Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS**						
17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	17	IS 13450 (Part 1)	S	One	Once in 03 years	For each type of manufactured during the period
202	**Electromagnetic disturbances – Requirements and tests**						
202	Electromagnetic disturbances – Requirements and tests	202	IS 13450-1-2	S	One	Once in 03 years	For each type of model manufactured during the period
208	General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	208	IS 13450-1-8	S	One	Once in 03 years	For each type of model manufactured during the period